IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	)	C.A. No. 21-691 (GBW) **REDACTED - PUBLIC VERSION**
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	)	C.A. No. 21-1138 (GBW) **REDACTED - PUBLIC VERSION**
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	)	C.A. No. 21-1594 (GBW) **REDACTED - PUBLIC VERSION**

JOINT SUPPLEMENTAL CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

A. Jazz's Introduction

The disputed term "gamma-hydroxybutyrate"/"oxybate" spans across two patent families. As set forth below, while Jazz's Sustained Release ("SR") Patents[1] use the disputed term in its plain and ordinary meaning, the '079/'782 Patents[2] provide lexicography for the disputed term. The dispute between the parties revolves around Avadel's amended non-infringement theory—specifically, Avadel has confirmed that it is arguing that the disputed term ***excludes sodium oxybate*** and means ***only*** the ***unbound*** anionic form of gamma-hydroxybutyric acid (Ex. 1 at 18, 37). Based on Avadel's confirmation, we have included the bracketed language in Avadel's Proposal below to highlight that the dispute is whether Jazz is entitled to the full scope of the disputed term or whether there is a disavowal of claim scope.

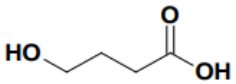
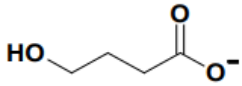
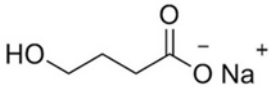
Claim Term	Jazz's Proposal	Avadel's Proposal
"gamma-hydroxybutyrate" (SR Patents)	Plain and ordinary meaning: i.e., (1) gamma-hydroxybutyric acid or (2) the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid	the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid [*excluding when ionically bound (e.g., in the form of sodium oxybate)*]
"gamma-hydroxybutyrate" / "oxybate" ('079/'782 Patents)	the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid	the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid [*excluding when ionically bound (e.g., in the form of sodium oxybate)*]

"Gamma-hydroxybutyrate"/"oxybate" has a well-understood plain and ordinary meaning: It means: (1) gamma-hydroxybutyric acid or (2) the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid (the "Anionic Form"). The Anionic Form is present when ionically bound, including as sodium oxybate. Ex. 2, Little ¶¶ 24-25. As depicted below, the

[1] U.S. Patent Nos. 10,758,488, 10,813,885, 10,959,956, and 10,966,931.

[2] U.S. Patent Nos. 11,077,079 and 11,147,782.

Anionic Form is the conjugate base of gamma-hydroxybutyric acid, meaning that it has a negative charge associated with an oxygen (within the carboxylic acid group) that would otherwise be bound to a hydrogen in gamma-hydroxybutyric acid. *Id.* ¶¶ 21-23. When in the form of gamma-hydroxybutyric acid, the Anionic Form does not exist (i.e., there is no negative charge) because an oxygen (within the carboxylic acid group) and hydrogen share electrons in what is called a covalent bond. *Id.* ¶ 23. But when in the form of, for example sodium oxybate, the Anionic Form exists (i.e., there is a negative charge) because an electrostatic attraction (ionic bond) is created between the oppositely, positively-charged sodium ion and the negatively-charged Anionic Form. *Id.* ¶ 24.

Gamma-hydroxybutyric acid	Anionic Form	Sodium Oxybate
		

As explained below, Jazz's SR Patents employ the full scope of the plain and ordinary meaning of "gamma-hydroxybutyrate": (1) gamma-hydroxybutyric acid or (2) the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid, including when ionically bound (e.g., in the form of sodium oxybate). In contrast, Jazz's '079/'782 Patents invoke lexicography to exclude gamma-hydroxybutyric acid, but not the ionically bound Anionic Form (e.g., oxybate salts/resins), from the plain and ordinary meaning.

B. Avadel's Introduction

The current dispute concerns whether "gamma-hydroxybutyrate"/"oxybate" (referred to herein interchangeably) should be given its plain and ordinary meaning, or if its meaning should be expanded, as Jazz proposes, to cover not just gamma-hydroxybutyrate itself, but also salts of gamma-hydroxybutyrate. Jazz contends that the term "gamma-hydroxybutyrate" includes "(1) gamma-hydroxybutyric acid or (2) the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid, ***including when ionically bound (e.g., in the form of sodium***

oxybate)." *Supra* at 2.[3] Jazz advances this position because it wants its patent claims (which are directed to oxybate) to also cover ***sodium*** oxybate. Indeed, Jazz's initial proposed construction of gamma-hydroxybutyrate[4] explicitly specified that it was "without exclusion as to bound gamma-hydroxybutyrate (*e.g.*, gamma-hydroxybutyrate salts or [resins])." Ex. A (3/17/2023 email). After realizing that this construction was at odds with clear lexicography and the usage of the terms in the claims, Jazz modified it to ostensibly mirror Avadel's construction. Ex. B (3/22/2023 email). However, Jazz's briefing makes clear that the substance of its original construction remains unchanged.

The Federal Circuit has repeatedly explained that claim construction starts with the claim language. Jazz's brief does the opposite, relegating its discussion of the claims to an afterthought. That is because the claim language in both patent families makes clear that gamma-hydroxybutyrate and salts of gamma-hydroxybutyrate are two distinct and non-overlapping substances. Thus, the claims of the Sustained Release patents recite formulations with an "active ingredient ***selected from*** gamma-hydroxybutyrate ***and*** pharmaceutically acceptable salts of gamma-hydroxybutyrate." *See* Ex. 3 ('488 patent), claim 1. If gamma-hydroxybutyrate covered salts of gamma-hydroxybutyrate, the claims' recitation of pharmaceutically acceptable salts would be surplusage. Similarly, the claims of Resinate patents refer separately to "oxybate" and "sodium oxybate." *See* Ex. 24 ('079 patent), claim 1 ("the single daily dose comprising an amount of ***oxybate*** equivalent to from 4.0 g to 12.0 g of ***sodium oxybate***"). It is black letter law—and basic grammar—that those distinct terms refer to two separate things.

[3] All emphasis throughout both parties' portions of this joint brief added unless otherwise indicated.

[4] Jazz initially proposed constructions for five terms, including "an amount of oxybate," and "a formulation of gamma-hydroxybutyrate." Ex. A.

Jazz largely ignores this claim language, and instead focuses its arguments on the alleged inoperability of the claims under Avadel's proposed constructions. But even if true, that cannot change the meaning of the term oxybate. In copying the subject matter of the asserted claims from Avadel's patent applications, Jazz disregarded (or missed) the fact that Avadel's patent specification expressly defines "gamma-hydroxybutyrate" to include pharmaceutically acceptable salts of gamma-hydroxybutyrate, making its claims fully operable. But Jazz's patent specifications lack the same lexicographic definition, and in some cases Jazz copied part but not all of the Avadel claim language, leaving in place language distinguishing gamma-hydroxybutyrate from salts of gamma-hydroxybutyrate. Thus, the disconnect between what the claim terms mean and what Jazz would like them to mean is a problem of Jazz's own making, not a basis to depart from looking "to the words of the claims themselves . . . to define the scope of the patented invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (citation omitted).

II. DISPUTED CONSTRUCTIONS

A. The Sustained Release Patents

1. "Gamma-hydroxybutyrate"

Term	Jazz's Proposed Construction	Avadel's Proposed Construction
"gamma-hydroxybutyrate"	Plain and ordinary meaning: i.e., (1) gamma-hydroxybutyric acid or (2) the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid	The negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid

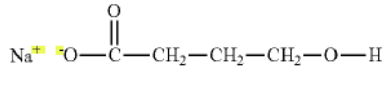
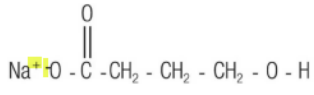
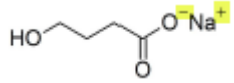
a) Jazz's Opening Position

There is no lexicography or disavowal for "gamma-hydroxybutyrate" in the SR Patents. Thus, Jazz "is entitled to the full scope of its claim language." *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004). That full scope is (1) gamma-hydroxybutyric acid or

(2) the Anionic Form of gamma-hydroxybutyric acid, including when ionically bound. Ex. 2, Little ¶¶ 20-26. All intrinsic evidence supports this plain meaning.

Specification: The first mention of gamma-hydroxybutyrate in the SR Patents demonstrates that gamma-hydroxybutyrate does not exclude the ionically bound Anionic Form, as Avadel contends. Ex. 2, Little ¶ 29. It states "[a]n example of a drug that is administered at a high dose, has a low molecular weight, and high water solubility, is gamma-hydroxy butyrate (GHB), ***particularly*** the sodium salt of GHB." Ex. 3 at 1:38-41. "The word particular is an adjective 'used to single out an individual member of a specified group or class.'" *Legacy Data Access, LLC v. MediQuant, Inc.*, No. 15-584, 2017 WL 6001637, at *13 (W.D.N.C. Dec. 4, 2017) (quoting Particular Definition, Oxford Dictionary, http://premium.oxforddictionaries.com/us/english/). In fact, the '488 patent discloses the "sodium salt of GHB" as one of the "***forms of*** GHB." Ex. 3 at 5:16-19. As Avadel's expert, Dr. Charman, stated: "The most common form of oxybate is the sodium salt form, known as sodium oxybate." Ex. 4, Charman ¶ 79.

A POSA would understand that just because the Anionic Form is ionically bound to sodium, does not mean that it loses its negative charge. Ex. 2, Little ¶¶ 24-25. This fact is depicted in the SR Patents' specification, Avadel's labeling, and Avadel's opening expert reports:

SR Patents' specification (Ex. 3 at 4:55-59)	**Avadel's labeling (Ex. 5 at AVDL_01330000)**	**Avadel's expert reports (Ex. 4, Charman ¶ 79; Ex. 6, Klibanov ¶ 34)**
		

The remainder of the SR Patents reinforce this plain meaning. *First*, the specification repeatedly cites publications that expressly include sodium oxybate within the scope of "GHB." *See, e.g.*, Ex. 3 at 1:42-58 ("GHB as a potential treatment for narcolepsy" and citing Mamelak 1977 (Ex. 7) at 273 ("Sodium γ-hydroxybutyrate (GHB) is [ ] remarkably safe. . . . We examined

its effects"); Broughton 1976 (Ex. 8) at 660 ("GHB was obtained as a banana-flavored syrup, GAMMA-OH")[5]; Broughton 1979 (Ex. 9) at 2 ("We chose the sodium salt of gamma-hydroxybutyrate (GHB)"); Broughton 1980 (Ex. 10) at 24 (explaining the study was a continuation of Broughton 1979)); Ex. 3 at 3:1-6 ("administration of GHB" and citing Liang 2006's (Ex. 11) administration of prototypes using Example 2's core that included "sodium gamma-hydroxybutyrate"); *see also* Ex. 11 at [0093]-[0096], [0114].

Second, the specification also includes many publications that refer to gamma-hydroxybutyric acid as "GHB," again demonstrating that Avadel is wrong that gamma-hydroxybutyrate is allegedly limited to the unbound Anionic Form. *See, e.g.*, Exs. 12-20 (disclosing "Gamma-hydroxybutyric acid (GHB)" or "γ-hydroxybutyric acid (GHB)"). Avadel's experts agree with the use of "GHB" to include gamma-hydroxybutyric acid. *See, e.g.*, Ex. 21, Langer ¶ 77 ("Liang 2006 discloses gamma hydroxybutyric acid ("GHB")").

Third, each Example in the specification uses gamma-hydroxybutyrate in salt form—sodium oxybate in Examples 1-11 and 13, and calcium oxybate in Example 12. Ex. 3 at 19:10-27:14. Construing "gamma-hydroxybutyrate" to exclude the ionically bound Anionic Form, including sodium oxybate, would exclude each and every Example from the inventions. "A claim construction that excludes the preferred embodiment[s] is rarely, if ever, correct. . . ." *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1290 (Fed. Cir. 2010) (internal citations/quotations omitted) (rejecting construction that "excludes the preferred embodiment and essentially all guaifenesin formulations").

[5] GAMMA-OH is the "sodium salt of gamma-hydroxybutyrate" that Broughton 1979 "chose" for its study. *See* Ex. 9 at 2-3.

The Asserted Claims: The claims require "[a] formulation comprising immediate release and sustained release portions, each portion comprising at least one pharmaceutically active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate, wherein . . ." the formulation/sustained release portion "releases [x%] of ***its gamma-hydroxybutyrate***." *See, e.g.*, Ex. 3 at 27:24-44. The antecedent basis for "***its*** gamma-hydroxybutyrate" is the gamma-hydroxybutyrate initially contained in the sustained release portion/formulation—i.e., the "active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate." In other words, the claims themselves make clear that sodium oxybate cannot be excluded from their scope, as Avadel proposes. Ex. 2, Little ¶ 30. The specification further explains this when discussing release profiles based on "the drug initially contained" within the dosage form. Ex. 3 at 5:63-6:8. Accordingly, the "gamma-hydroxybutyrate" that is released can be in the form of gamma-hydroxybutyric acid or salts of gamma-hydroxybutyric acid, of which sodium oxybate is one. This understanding is consistent with, as explained above, the SR Patents' Examples, which all include gamma-hydroxybutyric acid salts as the active ingredient, and which were assessed for the release of their active ingredient contents. *See id.* at 19:10-25:12, Figures 1-11, 3:7-47 (description of Figures). It is also consistent with, as explained below, the inventor's explanation of the release profile of the "GHB (as sodium oxybate)" example he provided to the Patent Office.

The dependent claims (e.g., claims 6 and 7 of the '488 patent) further reinforce that gamma-hydroxybutyrate salts (and sodium oxybate particularly) can be the active ingredient within, and therefore what is being released from, the formulation. *Id.* at 28:17-21; Ex. 2, Little ¶ 30. The recitation of sodium oxybate in dependent claims demonstrates that sodium oxybate is within the scope of, and cannot be excluded from, the independent claims. *See Allergan Sales, LLC v. Lupin*

Ltd., No. 11-530, 2013 WL 4519609, at *4 (E.D. Tex. Aug. 21, 2013) ("[C]laims 3, 4, and 5 . . . [e]ach recites 'the composition of claim 1 comprising 0.4% ketorolac tromethamine. . . .' 'ketorolac' as appearing in claim 1 must mean 'ketorolac tromethamine.'").

File Histories: The file histories also foreclose Avadel's attempt to exclude sodium oxybate. The Examiner rejected the '488 patent based on Liang 2006's disclosure of "a controlled release oral dosage form . . . comprising gamma-hydroxybutyric acid ('gamma-hydroxybutyrate') that may be in the form of its potassium or sodium salt." Ex. 22 at 10-11. Jazz overcame that rejection with an inventor declaration providing evidence of a different formulation than Liang 2006, "wherein the sustained release portion releases less than 10% of its GHB within the first hour and at least about 40% of its GHB by 4 to 6 hours when it is tested at a neutral pH (i.e., in DI water)." Ex. 23 at ¶ 10. The inventor identified "the dissolution profile of a sustained release portion of a ***GHB formulation meeting the limitations of the claims***," and stated that "[t]he sustained release portion contains ***GHB (as sodium oxybate)***." *Id.* at ¶ 13. Both the Examiner's and inventor's use of gamma-hydroxybutyrate expressly included sodium oxybate.

b) Avadel's Answering Position

(1) Scientific Background

The plain meaning of "gamma-hydroxybutyrate" is "the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid." '079 patent at 3:59-61; Ex. C (Klibanov Decl.) ¶¶ 9-14. A POSA would understand that in chemistry, the suffix "ate" is used to refer to an anion. Klibanov Decl. ¶ 8; Ex. D (Nomenclature of Organic Chemistry: IUPAC Recommendations and Preferred Names 2013) at 11 ("endings 'ate' or 'ite' [are used] to name anions"). Departing from that plain meaning to encompass salts would require a lexicographic definition, as found in Avadel's patent application (from which Jazz copied the claimed subject matter), but not found here. *See, e.g.*, Ex. E ('284 Publication) at ¶ [0152] ("When used herein

the term 'gamma-hydroxybutyrate'….refers to the free base of gamma hydroxy-butyrate, a pharmaceutically acceptable salt of gamma-hydroxybutyric acid, and combinations thereof…").

(2) Jazz's Effort To Encompass Salts Within The Claims Is Contradicted By The Claim Language

The parties' proposed constructions are below, presented to more clearly reflect the import of Jazz's proposed construction.

Claim Term	Jazz's Proposal[6]	Avadel's Proposal
Gamma-hydroxybutyrate (Sustained Release patents[7])	Plain and ordinary meaning: i.e., (1) gamma-hydroxybutyric acid or (2) the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid [***or (3) salts of gamma-hydroxybutyric acid***]	The negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid
Gamma-hydroxybutyrate/oxybate (Resinate patents[8])	The negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid [***and salts thereof***]	The negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid

"In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to particularly point out and distinctly claim the subject matter which the patentee regards as his invention." *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1354 (Fed. Cir. 2014). Notably, "[t]he written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir.

[6] Although Jazz asserts that it proposes "plain and ordinary meaning," Jazz revised its construction multiple times. *See* Ex. A; Ex. B. If Jazz were truly proposing the plain and ordinary meaning of a term, that meaning presumably would not be subject to change.

[7] U.S. Patent Nos. 10,758,488, 10,813,885, 10,959,956, and 10,966,931.

[8] U.S. Patent Nos. 10,077,079 and 11,147,782.

1995). The claims confirm that gamma-hydroxybutyrate does not encompass, nor is it present in, salts of gamma-hydroxybutyrate.

First, the claims recite a formulation comprising immediate and sustained release portions with "at least one pharmaceutically active ingredient selected from ***gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate***." *See, e.g.*, '488 patent, claim 1.

> 1. A formulation comprising immediate release and sustained release portions, each portion comprising at least one pharmaceutically active ingredient selected from ***gamma-hydroxybutyrate*** and ***pharmaceutically acceptable salts of gamma-hydroxybutyrate***, wherein:
>
> > a. the sustained release portion comprises a functional coating and a core, ….and the sustained release portion releases greater than about 40% of ***its gamma-hydroxybutyrate*** by about 4 to about 6 hours when tested in a dissolution apparatus 2 in deionized water at a temperature of 37° C. and a paddle speed of 50 rpm;
> >
> > …..
> >
> > c. the formulation releases at least about 30% of ***its gamma-hydroxybutyrate*** by one hour when tested in a dissolution apparatus 2 in deionized water at a temperature of 37° C. and a paddle speed of 50 rpm ….

The word "and" means "in addition to."[9] Thus, the ordinary meaning of the claim language indicates that "pharmaceutically acceptable salts of gamma-hydroxybutyrate" are compounds "in addition to," and thus distinct from, gamma-hydroxybutyrate itself. *See Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) ("Where a claim lists elements separately, the clear implication of the claim language is that those elements are distinct components.") (internal citations omitted). The claims confirm that gamma-hydroxybutyrate and salts of gamma-hydroxybutyrate are different things.

[9] Ex. F (https://www.yourdictionary.com/and).

Second, Jazz's contention that gamma-hydroxybutyrate covers "salts of gamma-hydroxybutyrate" would render the words "***and pharmaceutically acceptable salts of gamma-hydroxybutyrate***" surplusage. That is plainly disfavored. *See Digital-Vending Servs. Int'l, LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270, 1275 (Fed. Cir. 2012) (emphasizing the "importance of construing claim terms in light of the surrounding claim language, such that words in a claim are not rendered superfluous") (*citing Phillips*, 415 F.3d at 1314); *Merck & Co. v. Teva Pharms. USA, Inc.,* 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.").

Third, mirroring the distinction between gamma-hydroxybutyrate and salts of gamma-hydroxybutyrate, the claim goes on to require that the sustained release portion release "***its gamma-hydroxybutyrate***." The use of the possessive "its" indicates that the claim requires the release of the same gamma-hydroxybutyrate previously recited as present in the formulation. That is, a formulation with a sustained release portion that only contained a pharmaceutically acceptable salt of gamma-hydroxybutyrate could meet the preamble, but would not meet the "release" limitation because it does not contain any gamma-hydroxybutyrate.

While Jazz argues that the antecedent for "its gamma-hydroxybutyrate" must encompass both "gamma-hydroxybutyrate" and "pharmaceutically acceptable salts of gamma-hydroxybutyrate," *see supra* at 7, there is no justification for this tortured reading of the claim language, which makes clear that "gamma-hydroxybutyrate" in the release limitation refers back to the exact same "gamma-hydroxybutyrate" in the preamble. *See Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229, 1237 (Fed. Cir. 2016) ("claim construction [should] give meaning to all of a claim's terms").

Fourth, any uncertainty as to whether "gamma-hydroxybutyrate" can cover "pharmaceutically acceptable salts of gamma-hydroxybutyrate" is settled by claim 12, which Jazz ignores. "Differences among claims can also be a useful guide in understand the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. Claim 12, like claim 1, recites a formulation of at least one pharmaceutically acceptable ingredient selected from "gamma-hydroxybutyrate" and "pharmaceutically acceptable salts of gamma-hydroxybutyrate." *See* '488 patent at 28:47-49. Unlike claim 1, however, claim 12 recites that the "formulation releases [30%] of ***its gamma-hydroxybutyrate or salt thereof*** by one hour." *Id.* at 28:61-62. Thus, Claim 12 demonstrates that when Jazz intended to claim a formulation that releases ***either*** gamma-hydroxybutyrate ***or pharmaceutically acceptable salts of*** gamma-hydroxybutyrate present in the formulation, it knew how to do so. Jazz's contention that gamma-hydroxybutyrate should be construed to encompass both gamma-hydroxybutyrate ***and*** salts of gamma-hydroxybutyrate would result in claim 12 reciting a formulation that releases 30% "of its gamma-hydroxybutyrate ***or salt thereof*** or salt thereof by one hour," rendering the "or salt thereof" surplusage.

By comparison, other clauses in claim 12 recite release of only gamma-hydroxybutyrate ("the sustained release portion releases greater than about 40% of its gamma-hydroxybutyrate by about 4 to 6 hours"). *Id.* at 28:55-60. Jazz's proposal would improperly read out the distinction between the release of "gamma-hydroxybutyrate" in some limitations, and release of "gamma-hydroxybutyrate or salts thereof" in others. Such a construction should be rejected. *See Digital-Vending*, 672 F.3d at 1275; *Merck*, 395 F.3d at 1372.

Fifth, Avadel's proposed construction—"the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid"—accurately captures the distinction reflected in the claims between gamma-hydroxybutyrate and salts of gamma-hydroxybutyrate, and avoids

violating the multiple canons of claim construction that are at odds with Jazz's proposal. It also reflects the fact that gamma-hydroxybutyrate and salts of gamma-hydroxybutyrate, such as sodium oxybate, are distinct entities with different properties and different molecular identities.[10] Klibanov Decl. ¶¶ 9-11. As Dr. Klibanov explains, while ionic compounds such as sodium oxybate may sometimes be illustrated as retaining their full positive and negative charges, it would be overly simplistic to view the gamma-hydroxybutyrate anion and the sodium cation as independent molecular entities associated with each other within the sodium oxybate molecule. *Id*. at ¶¶ 12-14. In solid sodium oxybate, neither the sodium nor the oxybate ion exists in the same form as it would when unbound and separate. *Id*. Consistent with this concept, Jazz recognizes that the anionic form of gamma-hydroxybutyrate "does not exist" when gamma-hydroxybutyrate binds to a hydrogen atom to form gamma-hydroxybutyric acid.[11] *Supra* at 1-2.

Finally, Jazz's citation to the recitation of specific salts in claims 6 and 7 (*supra* at 7-8) does not require a different outcome. Claim 1, from which claims 6 and 7 depend, recites a formulation that can contain both gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate, such as those specific salts recited in claims 6 and 7. Thus, claims 6 and 7 do not support Jazz's construction. Klibanov Decl. ¶¶ 25-28.

[10] Jazz's citations to instances where sodium gamma-hydroxybutyrate is colloquially referred to as a form of gamma-hydroxybutyrate (*supra* at 5) do not alter that gamma-hydroxybutyrate and salts of gamma-hydroxybutyrate are two distinct molecular entities, and more importantly, do not overcome the plain language of the claims which proves that the two are distinct.

[11] Avadel's position is that the term gamma-hydroxybutyrate should not be construed differently across the Sustained Release and Resinate patent families as Jazz proposes, and that gamma-hydroxybutyrate is a distinct entity from gamma-hydroxybutyric acid. However, Avadel does not object to including "gamma-hydroxybutyric acid" in the construction of gamma-hydroxybutyrate in the Sustained Release patents solely to simplify the issues for the Court and because it does not impact any dispute between the parties.

(3) The Specification Cannot Overcome The Clear Claim Language

Rather than start with the language of the claims, Jazz invites the Court to err by beginning with the specification, and then focusing on a subset of the disclosures and cited references. This attempt fails for multiple reasons.

First, Jazz's assertion that "[t]here is no lexicography or disavowal" (*supra* at 4) inverts the pertinent inquiry. Given that the claims unambiguously confirm the distinction between "gamma-hydroxybutyrate" and "salts thereof," there can be no departure from that ordinary meaning without lexicography or disavowal. *Thorner v. Sony Computer Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (explaining that "[t]he words of a claim are generally given their ordinary and customary meaning" unless the patentee acts as his own lexicographer or expressly disavows claim scope). Jazz's concession that none exists therefore ends the inquiry.

Second, Jazz's assertion that "the specification repeatedly cites publications that expressly include sodium oxybate within the scope of 'GHB'" (*supra* at 5-6), is of no moment. The specification also distinguishes between gamma-hydroxybutyrate and salts thereof. *See, e.g.*, '488 patent at 5:35-38 ("the drug incorporated in such compositions may be selected from GHB and pharmaceutically acceptable salts…of GHB"). The existence of equivocal uses—particularly in secondary references—does not qualify as lexicography. *See Baxalta Inc. v. Genentech, Inc.*, 972 F.3d 1341, 1349 (Fed. Cir. 2020) ("[T]he standard for lexicography is exacting, requiring the patentee to 'clearly express an intent' to redefine a term.'"); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1347 (Fed. Cir. 2003) ("[A] patentee does not renounce the ordinary meaning of a term merely by submitting a reference that employs a different meaning.").

Third, even were the specification clear (and it is not), that would not trump the primary import of the claim language, which unambiguously draws a distinction between gamma-hydroxybutyrate and salts of gamma-hydroxybutyrate. *Elekta Instrument S.A. v. O.U.R. Scientific Intern., Inc.*, 214 F.3d 1302, 1308 (2000) ("[T]he unambiguous language of the amended claim controls over any contradictory language in the written description."). Jazz's citation to the file history of the Sustained Release patents is equally unavailing. *Supra* at 8. "Claim language and the specification generally carry greater weight than the prosecution history," and Courts have cautioned against relying on the prosecution history too heavily for purposes of construing the claims. *HTC Corp. v. IPCom GmbH & Co., KG*, 667 F.3d 1270, 1276 (Fed. Cir. 2012).

Fourth, Jazz's assertion that the ordinary meaning "would exclude each and every Example from the inventions" (*supra* at 6) is misleading. None of those examples would be covered by the claims of the Sustained Release patents ***even under Jazz's proposed construction***. The specification of the Sustained Release patents does not contain a single description of a formulation comprising a sustained release portion that includes a functional coating ***comprising methacrylic acid methyl-methacrylate***, let alone one exhibiting the release profile recited in the claims when tested under the claimed dissolution conditions. *See* '488 patent, Examples 1-13; *see also* Ex. 22 ('488 patent prosecution history) at 8 ("None of the compositions disclosed by Examples 1-12 are even within the scope of the claims.").

Finally, the alleged problems Jazz identifies (*supra* at 6) with the construction of "gamma-hydroxybutyrate" proposed by Avadel—and required by the claim language—are the direct result of Jazz's copying the claimed subject matter from Avadel. During prosecution of the Sustained Release patents, Jazz replaced its then-pending claims with claims that attempted to cover the subject matter disclosed in Avadel's newly-published '284 Publication which matured into

Avadel's Patent No. 10,272,062. Jazz's new claims included the requirement that the formulation release "at least about [x%] of ***its*** gamma-hydroxybutyrate"—language that Jazz lifted directly from the claims of Avadel's '284 Publication. *See e.g.*, Ex. E ('284 Publication), claim 4 ("the formulation releases at least 80% of its gamma-hydroxybutyrate at 3 hours"). However, Jazz failed to account for the fact that Avadel's specification did not use the ordinary meaning of the term and instead defined gamma-hydroxybutyrate to include both gamma-hydroxybutyrate and "a ***pharmaceutically acceptable salt*** of gamma-hydroxybutyric acid." *Id*. at ¶ [0152]. Because Jazz's specification contained no such corresponding definition, Jazz's resulting claims required the release of gamma-hydroxybutyrate—but not salts of gamma-hydroxybutyrate—from the claimed formulation. Jazz's careless copying, not Avadel's proposed construction, resulted in claims that do not align with the few formulations described in specification.

c) Jazz's Reply Position

Avadel agrees that there "can be no departure from [the] ordinary meaning without lexicography or disavowal." And the parties agree there is no lexicography or disavowal here. *See* Ex. 36 at 15:3-12, 18:6-19:1 (Dr. Klibanov confirming no lexicography or disavowal). The parties therefore agree that the plain and ordinary meaning of "gamma-hydroxybutyrate" should control for the SR Patents, but dispute what that meaning is. Jazz proposes gamma-hydroxybutyric acid and the gamma-hydroxybutyrate anion, not excluding when that anion is in bound form. Avadel proposes the anion, unbound, alone, and nothing else. Both parties' experts—consistent with the SR Patents' specification, file histories, and prior art—agree Jazz's proposal is the "common usage" of "gamma-hydroxybutyrate." That should end this inquiry.

(1) Avadel's Expert Agrees Jazz's Proposal Is The Common Usage

Dr. Klibanov admitted, consistent with Jazz's proposal, that the "common usage of gamma-hydroxybutyrate" "refer[s] to sodium gamma-hydroxybutyrate and . . . to gamma-hydroxybutyric acid." *Id.* at 158:11-159:18. Indeed, Dr. Klibanov reviewed references—including by another Avadel expert, Dr. Scharf—that use "gamma-hydroxybutyrate" to refer to sodium oxybate and gamma-hydroxybutyric acid. *See, e.g.*, Ex. 37. Dr. Klibanov conceded: "people sometimes use – in – in the literature use 'gamma hydroxybutyrate' to refer to sodium gamma-hydroxybutyrate and sometimes, again, commonly use it in the literature to refer to gamma-hydroxybutyric acid." Ex. 36 at 159:7-18; *see also* Ex. C, ¶ 15. This "common[] use" is consistent with only Jazz's construction.[12]

Although both parties agree the plain meaning should apply, Dr. Klibanov then claimed that, "regardless [of] whatever ***common usage*** may have been" in the specification or prior art, his position and Avadel's construction "are limited to the meaning of the claim term 'gamma-hydroxybutyrate.'" Ex. 36 at 117:9-16; *see also id.* at 13:1-22, 20:21-21:18. Dr. Klibanov admitted, however, that Avadel's construction is not "necessarily [reflective of] the meaning of the term 'gamma-hydroxybutyrate' as it has been used" by POSAs. *Id.* at 113:23-117:21, 124:5-8. As noted above, that should end this dispute.

(2) The Intrinsic and Extrinsic Evidence Supports Only Jazz

Avadel contends that notwithstanding how "gamma-hydroxybutyrate" is commonly used, "gamma-hydroxybutyrate" must be construed in the claims to mean the anion, unbound, alone,

[12] Avadel mischaracterizes Jazz's proposal before its opening brief. Jazz originally proposed construing phrases (e.g., "releases its gamma-hydroxybutyrate") without construing "gamma-hydroxybutyrate," but then amended its proposal so that the parties were presenting the same terms to the Court.

and nothing else. *Id.* 13:19-22 ("I'm opining on . . . what this term means in the claims of…the patents. Whatever meaning may take place elsewhere, that's just not something that I have focused on."). But "[t]he customary meaning of a claim term is not determined in a vacuum and should be harmonized, to the extent possible, with the intrinsic record, as understood within the technological field of the invention." *Lexion Med. v. Northgate Techs.*, 641 F.3d 1352, 1356 (Fed. Cir. 2011). Only Jazz's proposal is so harmonized.

Starting with the claims, Avadel's proposal would read out limitations providing that the formulation may comprise pharmaceutically acceptable salts of gamma-hydroxybutyrate. According to Avadel, a formulation containing such salts "could meet the preamble, but would not meet the 'release' limitation because it does not contain any gamma-hydroxybutyrate."[13] In other words, under Avadel's interpretation, the claims explicitly contemplate gamma-hydroxybutyrate salts as an active ingredient, but fail to allow for its release. That would render claim language directed to formulations of gamma-hydroxybutyrate salts meaningless.

The specification similarly supports only Jazz; it discusses properties of gamma-hydroxybutyrate, such as its solubility and hygroscopicity, which only make sense (as Dr. Klibanov admitted) if "gamma-hydroxybutyrate" includes its bound forms. Both experts agree that the unbound anion (i.e., Avadel's proposed construction) cannot exist as a solid. *See* Ex. 2 at ¶ 25; Ex. 36 at 17:24-18:5, 64:9-11; Ex. 41 at 8:4-10, 71:18-21, 93:8-23, 123:11-124:16, 128:1-130:3.[14] Consequently, Dr. Klibanov admitted that each discussion of gamma-hydroxybutyrate's

[13] Avadel wrongly implies that salts of gamma-hydroxybutyrate appear only in the preamble; they also appear throughout the claims.

[14] Dr. Klibanov's only rebuttal was that the unbound anion can exist in a "gel," and that a "gel" is solid. Ex. 36 at 41:5-13. This theory is not in Avadel's brief or Dr. Klibanov's declaration. Avadel's counsel also refused to let Dr. Klibanov answer when he allegedly developed his "gel" theory on alleged privilege grounds. *Id.* at 93:15-94:14. Regardless, the SR (continued…)

solubility or hygroscopicity in the SR Patents was referring to, consistent with Jazz's construction, a solid gamma-hydroxybutyrate form (e.g., sodium oxybate), not Avadel's unbound anion construction:

> **Q.** In the bottom of column 4 of the '488 patent where it says, "For instance, GHB is very soluble," what would a POSA understand 'GHB' there to mean?
>
> **A.** A POSA would understand that this is yet another example of loose talk on the part of the patentees, and that ***what they're really referring to is salts***, and probably – most likely a sodium salt of gamma-hydroxybutyrate.

Ex. 36 at 64:20-65:2; *id.* at 25:14-27:12, 59:16-64:11. Dr. Klibanov testified that the '079/'782 Patents' specification similarly "makes no sense" if the ordinary usage of "gamma hydroxybutyrate" were to exclude the ionically bound form:

> **Q.** And even when [the specification] just says "gamma-hydroxybutyrate' alone, without sodium in front of it, it's referring to sodium oxybate?
>
> **A.** It ***must refer to sodium oxybate*** because otherwise it makes no sense.

Id. at 56:23-57:8; *id.* at 57:9-58:9. Further, when asked to identify anywhere in the SR Patents that "says that gamma-hydroxybutyrate means the negatively charged or anionic form of gamma-hydroxybutyrate unbound to anything else," Dr. Klibanov could not do so. *Id.* at 16:17-17:7, 76:3-20. Nor does Avadel cite any such passage.

Finally, the prosecution history forecloses Avadel's proposal. There, the inventor made clear—consistent with Dr. Klibanov's admitted "common usage"—that "[t]he sustained release portion contains GHB (***as sodium oxybate***)." *Id.* at 106:7-107:18. Dr. Klibanov admitted the inventor "says what -- what he says. He says, 'The sustained release portion contains GHB (as sodium oxybate).' That's what he says" (*id.* at 105:20-106:21), but Avadel impermissibly ignores

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Patents are silent on gel formulations, and another Avadel expert previously opined that gel formulations are not described in the SR Patents. Ex. 38 at ¶ 221. Moreover, Dr. Little explained that unbound anions, alone, do not exist in gels. Ex. 41 at 133:19-134:24, 135:9-139:10, 140:16-141:14.

that intrinsic evidence (*id.* at 103:19-104:3). *See Rembrandt Innovations v. Apple, Inc.*, 716 Fed. App'x 965, 971 (Fed. Cir. 2017) (holding it appropriate to "disregard testimony from [an] expert that contradicts the claims' meaning established by the intrinsic evidence").

(3) Alleged "Redundancy" Does Not Favor Avadel

Avadel argues "black letter law" and "basic grammar" require that "gamma-hydroxybutyrate" and "salts of gamma-hydroxybutyrate" must "refer to two separate things." That is not "black letter law." "While a construction that introduces redundancy into a claim is disfavored, it is not foreclosed. That is particularly true where, as in this case, intrinsic evidence makes it clear that the [alleged] 'redundant' construction is correct." *VLSI Tech. v. Intel Corp.*, 53 F.4th 646, 653 (Fed. Cir. 2022). "[O]verlap in the limitations that results from giving them their plain meaning does not justify importing a [negative] limitation into the claims where such a limitation has no support in the specification or the prosecution history." *Los Angeles Biomedical Rsch. Inst. v. Eli Lilly & Co.*, 849 F.3d 1049, 1064 (Fed. Cir. 2017). While there is a "preference for a construction that gives meaning to all the terms of a claim rather than a construction that causes some surplusage, ***even worse*** would be a construction clearly at odds with the specification." *Robocast, Inc. v. Microsoft Corp.*, No. 10-1055, 2013 WL 3294862, at *13 (D. Del. June 28, 2013).

Nor does "basic grammar" demand Avadel's construction. Avadel states that the claims "require that the sustained release portion release '***its gamma-hydroxybutyrate***,'" and that "[t]he use of the possessive ***'its'*** indicates that the claim requires the release of the same gamma-hydroxybutyrate previously recited as present in the formulation." But "basic grammar" indicates then that the formulations release "gamma-hydroxybutyrate" from a sustained release portion where the active ingredient has been "selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate." As Dr. Klibanov admitted, if

sodium oxybate dissolves in water (the claimed release media), it will release gamma-hydroxybutyrate. Ex. 36 at 87:24-88:9. When asked "where does the 'gamma-hydroxybutyrate' as you've defined it come from," Dr. Klibanov admitted: "It comes from sodium gamma-hydroxybutyrate." *Id.* at 100:17-101:17. As Dr. Klibanov's testimony demonstrates, Avadel's argument that a formulation "with a sustained release portion that only contained a pharmaceutically acceptable salt of gamma-hydroxybutyrate could meet the preamble, but would not meet the 'release' limitation because it does not contain any gamma-hydroxybutyrate," is incorrect.

Avadel attempts to rely on claim 12 of the '488 patent. That a single limitation, in a single independent claim, states the release of gamma-hydroxybutyrate "or a salt thereof" does not mean that no other claim permits the release of gamma-hydroxybutyrate salts when all other intrinsic evidence demonstrates otherwise. *See* Ex. 41 at 100:1-102:19. The Federal Circuit has "been cautious in assessing the force of claim differentiation in particular settings, recognizing that patentees often use different language to capture the same invention, discounting it where it is invoked based on independent claims rather than the relation of an independent and dependent claim, and not permitting it to override the strong evidence of meaning supplied by the specification." *Atlas IP, LLC v. Medtronic*, Inc., 809 F.3d 599, 607-09 (Fed. Cir. 2015) (reversing where district court "did not rely on anything for its construction except the claim words understood in isolation.").

Moreover, Avadel largely ignores dependent claims 6 and 7—formulations where the active ingredient is a salt of gamma-hydroxybutyrate. Avadel argues the formulations can include sodium oxybate, they just cannot release it. That is both incorrect and nonsensical. "A claim

construction that renders asserted claims facially nonsensical cannot be correct." *Neville v. Found. Constructors, Inc.*, 972 F.3d 1350, 1357 (Fed. Cir. 2020).

Avadel argues a nonsensical construction is acceptable because of alleged "careless copying" by Jazz from an Avadel patent application. While unsupported and incorrect, this is a red herring. A court construing a patent claim seeks to accord a claim the meaning it would have to a POSA "***at the time of the invention***, i.e., as of the effective filing date." *Phillips*, 415 F.3d at 1313. This inquiry is "an objective" one. *Id.* Therefore, the Court assesses whether Avadel's proposal is nonsensical (which it is) in view of the specification and other evidence that would have been available to a POSA as of the priority date (no later than March 2011)—not based upon a patent application filed years later.

Dr. Klibanov confirmed the claims would be nonsensical under Avadel's proposal. He testified that the unbound anion "cannot exist in a solid form, and, therefore, cannot be weighted out," including in "milligram amounts or gram amounts." Ex. 36 at 114:22-115:9. But each claim expresses "gamma-hydroxybutyrate" that is "weighted out" in "milligram amounts or gram amounts." By Dr. Klibanov's admission, these claims only make sense if gamma-hydroxybutyrate includes bound forms (e.g., sodium oxybate).

d) Avadel's Sur-Reply Position

Jazz's briefing repeatedly includes "bound forms" of gamma-hydroxybutyrate in its proposed construction. *Supra* at 16-18. The Court should see this for what it is: a feeble effort to dress in scientific jargon Jazz's untenable position that the term "gamma-hydroxybutyrate" includes "salts of gamma-hydroxybutyrate" (as Jazz's expert admitted). *See* Ex. I (Little Tr.) at 61:20-62:8; 67:22-69:7; 98:25-99:8. Jazz offers no cogent response to the fact that basic grammar dictates that the claims' use of "gamma-hydroxybutyrate" followed by "***and*** pharmaceutically acceptable salts" means that the former is distinct from, and does not include, the latter. Nor does

Jazz address Federal Circuit authority that the "clear implication" of separately listed claim elements is that they are "distinct components." *Becton*, 616 F.3d at 1254; *see also Canopy Growth Corp. v. GW Pharma Ltd.*, No. 2022-1603, 2023 WL 3048243, at *4 (Fed. Cir. Apr. 24, 2023) ("[T]here is no reason to include an alternative in a Markush group that falls entirely within another alternative."); *Shire Dev., LLC v. Watson Pharm, Inc.*, 787 F.3d 1359, 1366 (Fed. Cir. 2015); *Gaus v. Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir. 2004). Jazz invites error in asking to construe "gamma-hydroxybutyrate" to include the separately listed "salts of gamma-hydroxybutyrate."

Claim 12 resolves any doubt that "gamma-hydroxybutyrate" is not coextensive with "salts of gamma-hydroxybutyrate" by reciting release of "30% of its gamma-hydroxybutyrate ***or salt thereof***." Ex. 3 ('488 patent), claim 12. Given that "or" "indicate[s] an alternative,"[15] the claim recites a choice between releasing two distinct things: gamma-hydroxybutyrate ***or*** a salt of gamma-hydroxybutyrate. *Id.* Were Jazz correct, the claim would read "30% of its gamma-hydroxybutyrate [or salt thereof] ***or salt thereof***." Even Jazz's expert admitted as much. Little Tr. at 106:07-107:19.

Jazz's suggestion that this is a mere presumption associated with "claim differentiation" is a strawman.[16] *Supra* at 21. Claim 12 demonstrates that when Jazz intended to claim a formulation that releases "gamma-hydroxybutyrate ***or*** salts thereof" it did so by reciting "salts thereof." When it did not do so (claim 1), "gamma-hydroxybutyrate" means just that, and should not be contorted

[15] Ex. M (https://www.merriam-webster.com/dictionary/or).

[16] In any event, Jazz's reliance on *Atlas* is inapposite. The claims there included language that "avoids a conclusion of superfluousness" under the disputed construction. 809 F.3d at 607. By contrast, Jazz's construction would render the claim term "salts" entirely superfluous. Little Tr. at 106:11-107:19; Ex. C (Klibanov Decl.) at ¶¶ 22-23.

to include the "salt thereof" language. Jazz offers no way to reconcile claim 12's use of "salts thereof" with its proposed construction.

Jazz instead claims that redundancy is acceptable. *Supra* at 20. But Jazz's cited cases involved a lexicographic definition (*VLSI Tech*, 53 F.4th at 652-53), or an applicant's explanation during prosecution that the purportedly redundant term was meant as a clarification (*Robocast*, 2013 WL 3294862, at *13).[17] Neither circumstances exist here: the claim structure aligns directly with what the Federal Circuit has endorsed as indicating "distinct components."

Jazz next cites Dr. Klibanov's testimony as purportedly indicating that "gamma-hydroxybutyrate" is sometimes imprecisely used to refer to its salts. *Supra* at 17. But the claim construction inquiry focuses on the ordinary meaning in the *context of the intrinsic record*—most importantly, the claim language.[18] *See Phillips*, 415 F.3d at 1314. Dr. Klibanov was adamant that the plain meaning of "gamma-hydroxybutyrate" *in the context of the claims* means what Avadel proposes. Even Dr. Little repeatedly confirmed that the term "gamma-hydroxybutyrate" had to be construed in the context in which it is used. *See* Little Tr. at 80:4-16, 100:14-103:5, 107:9-19. The claims make clear that "gamma-hydroxybutyrate" and "salts of gamma-hydroxybutyrate" are distinct. Neither the specification nor the single sentence Jazz cites from the prosecution history[19] change the import of the claim language. *See Braintree Labs.*, 749 F.3d at 1354 ("In construing

[17] *L.A. Biomedical* did not criticize a "negative limitation" as Jazz contends (*supra* at 20), and in fact rejected a construction because the "separate use" of two terms "gave rise to the inference" that one is not implicit in the other. 849 F.3d at 1063.

[18] The literature is at best ambiguous. Jazz's cherry-picked references use the abbreviation "GHB" (not "gamma-hydroxybutyrate" or "oxybate") to encompass multiple discrete entities. Given that GHB is not a claim term, it has little relevance.

[19] The prosecution history is equivocal. During prosecution, Jazz introduced claim 12 which emphasizes a choice between "gamma-hydroxybutyrate ***or*** pharmaceutically acceptable salts." Ex. J (Request for Continued Examination) at Claim 121. Moreover, even if Dr. Allphin's declaration can be considered inventor testimony, it is entitled to little weight.

claims, the analytical focus must begin and remain centered on the language of the claims themselves...").

Jazz's complaint that Avadel's construction renders the claims inoperable,[20] is explained by Jazz's haphazard copying and does not mean that the claims should be construed to save them from invalidity. *Supra* at 15-16; *see Chef Am., Inc. v. Lamb–Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) ("Even a non-sensical result does not require the court to redraft the claims…"). Upon filing the '488 patent application, Jazz cancelled its pending claims (Ex. L), and filed new claims reciting release of gamma-hydroxybutyrate, directly tracking Avadel's patent publication, which published six months earlier. *See* Ex. E ('284 publication). Jazz cites no case counselling the Court to save Jazz from itself in these circumstances by applying a construction that contradicts the claim language. Jazz's suggestion that the Court ignore Jazz's copying and only look to "evidence that would have been available to a POSA of the priority date," *Supra* at 22, makes no sense, because it would also prevent the Court from considering ***the claims themselves***, which did not exist as of March 2011.

B. The '079 and '782 patents

1. "Gamma-hydroxybutyrate"/"Oxybate"

Term	Jazz's Proposed Construction	Avadel's Proposed Construction
"gamma-hydroxybutyrate" / "oxybate"	The negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid	The negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid

[20] If that were truly the case, Jazz would not continue to refuse agree not to assert infringement under Avadel's proposed construction. Ex. K.

a) Jazz's Opening Position

Unlike the SR Patents, the '079/'782 Patents provide lexicography for "gamma-hydroxybutyrate"/"oxybate." "As used [t]herein, the term gamma-hydroxybutyrate (GHB) or 'oxybate' refers to the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid." Ex. 24 at 3:59-61. Therefore, a POSA would understand that, unlike the SR Patents, the use of "gamma-hydroxybutyrate"/"oxybate" in the '079/'782 Patents does not include gamma-hydroxybutyric acid. *See* Ex. 2, Little ¶¶ 32-33. But a POSA would ***not*** conclude that gamma-hydroxybutyrate/oxybate means only the unbound Anionic Form, to the exclusion of oxybate salts or resins. *Id.* ¶¶ 34-38. Nor would a limitation to only the unbound Anionic Form, so as to exclude oxybate salts and resins, be supported by the intrinsic record. *Id.*

Specification: *First*, the '079/'782 Patents' specification repeatedly discusses sodium oxybate and cites sodium oxybate publications when discussing "GHB." For example, immediately after stating that "gamma-hydroxybutyrate" refers to the Anionic Form, the specification discusses "Xyrem" (Jazz's sodium oxybate product) and "GHB" interchangeably: "An effective dosage range of Xyrem is 6 g to 9 g, given at night in divided doses . . . GHB is typically given twice nightly due to a short in vivo half-life." Ex. 24 at 3:59-4:3. The specification further states that GBL "is a prodrug for GHB" and that "GBL can be hydrolyzed . . . to produce GHB," and cites to references that discuss only the production of sodium oxybate from GBL. *Id.* at 5:14-26 (citing Arena 1980 (Ex. 25) and Lettieri 1978 (Ex. 26)).

Second, the '079/'782 Patents' specification states that the inventions include ionically "bound" gamma-hydroxybutyrate/oxybate, including oxybate resins and "oxybate salts, such as sodium, calcium, potassium, or magnesium." *See, e.g.*, Ex. 24 at 4:56-61, 9:30-35, 11:45-51, 15:30-35, 16:2-5, 16:26-29, 19:4-7; *see also id.* at 6:4-11 (describing the invention as "suspensions of oxybate-containing particles").

Third, all Examples in the '079/'782 Patents' specification include only ionically bound oxybate (oxybate resins). *See id.* at 22:24-24:55. Adopting Avadel's proposal would exclude each and every Example.

The Asserted Claims: Each claim requires that the gamma-hydroxybutyrate/oxybate begin as a solid formulation. The '079 patent requires "opening a sachet containing a ***solid*** oxybate formulation" (*see* Ex. 24 at 24:57-63), and the '782 patent requires "***particles*** comprising gamma-hydroxybutyrate" (*see* Ex. 27, '782 Patent at 25:14-18). Unbound anions do not exist as solids. Ex. 2, Little ¶¶ 24-25, 34. The Anionic Form of gamma-hydroxybutyrate/oxybate therefore must be ionically bound to something in the solid form—either a salt or resin in the context of the '079/'782 Patents. *Id.* ¶¶ 34-36.[21]

Avadel's proposal would render the asserted claims scientifically impossible to achieve. "[A] construction that renders the claimed invention inoperable should be viewed with extreme skepticism." *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 275 F.3d 1371, 1376 (Fed. Cir. 2002), *vacated and remanded on other grounds,* 537 U.S. 802 (2002); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1053 n.1 (Fed. Cir. 2010) (rejecting construction where "the claimed invention would be inoperable if the claims are construed in the manner suggested").

Avadel's proposal would further be nonsensical within the context of the claims as a whole given that all claims of the '079 patent and certain claims of the '782 patent require "an amount of [gamma-hydroxybutyrate/oxybate]" "equivalent to" certain amounts of "sodium [gamma-hydroxybutyrate/oxybate]." *See, e.g.*, Ex. 24 at 24:60-62; Ex. 27 at 25:42-57. A POSA would

[21] In fact, Avadel previously incorrectly argued that the claims of the '079/'782 Patents covered ***only*** resinate compositions. The Court construed the controlled and modified release terms in these patents to include, but not be limited to, resinate compositions. D.I. 229 at 11, 13-14. Under Avadel's new proposal, the claims would not cover ***any*** resinate compositions.

understand that the amount of the unbound Anionic Form equivalent to a certain amount of sodium gamma-hydroxybutyrate/oxybate could be calculated based on the different molecular weights of the unbound Anionic Form (103.1 g/mol) and sodium gamma-hydroxybutyrate/oxybate (126.0 g/mol). Ex. 2, Little ¶ 37. Therefore, the equivalent amount of the unbound Anionic Form would always be the same as the equivalent amount of sodium gamma-hydroxybutyrate/oxybate, and that amount of the unbound Anionic Form could just be claimed without the need to calculate any "equivalency" to sodium oxybate. *Id.* It would only make sense to include the "equivalent" amounts of sodium gamma-hydroxybutyrate/oxybate if the form of the "gamma-hydroxybutyrate"/"oxybate' could be different and have different molecular weights depending on which cation the Anionic Form is ionically bound to—e.g., potassium oxybate (142.2 g/mol), calcium oxybate (246.27 g/mol), sodium oxybate (126.0 g/mol), etc. *Id.*

File Histories: The file histories further reinforce the specification's use of gamma-hydroxybutyrate/oxybate as not excluding oxybate salts/resins. Both the Examiner's and inventor's use of gamma-hydroxybutyrate/oxybate expressly included ionically bound (i.e., salt forms of) oxybate. *See, e.g.*, Ex. 28 at 5 (examiner rejecting '079 patent based on reference "directed to sodium oxybate"); Ex. 29 at 9 (Jazz arguing against rejection because "oxybate ***salts*** [are] known to be deliquescent solid"); Ex. 30 at ¶ 4 (inventor declaration arguing against rejection because "oxybate ***salts*** are known to be hygroscopic"); Ex. 31 at 6 (examiner rejecting '782 patent based on reference disclosing GHB salts); Ex. 32 at 7-8 (Jazz arguing against rejection because the reference teaches a "GHB-containing formulation" (GHB salts), but not the other elements of the '782 patent's claims).

b) Avadel's Answering Position

The Resinate patents provide a clear lexicographic definition for gamma-hydroxybutyrate/oxybate: "the negatively charged or anionic form (conjugate base) of gamma

hydroxybutyric acid." *See, e.g.*, '079 patent at 3:59-61. That definition makes no mention of salts of gamma-hydroxybutyrate. Consistent with that clear lexicography, the claims unambiguously distinguish between "oxybate" (the anion) and the "sodium oxybate."[22] *See* '079 patent, claim 1 (reciting "administering a dose of ***oxybate*** to a patient equivalent to from 4 to 12 g of ***sodium oxybate***"); Klibanov Decl. at ¶¶ 31-33. While Jazz suggests that its proposal simply adopts the lexicographic definition of oxybate recited in the Resinate patents, Jazz is in fact trying to expand the term to cover sodium oxybate, at odds with the specification and the claims.

As with the Sustained Release patents, Jazz's reliance on the use of gamma-hydroxybutyrate in the specification and the file history of the Resinate patents cannot overcome the "unambiguous language" of the claims. *Elekta*, 214 F.3d at 1308. And it certainly cannot overcome the lexicographic definition for oxybate in the specification of the Resinate patents, which does not include oxybate salts.

Nor does the specification support Jazz's construction. For example, the specification's reference to gamma-hydroxybutyrate's administration "twice nightly due to its short in vivo half-life" (*supra* at 26) simply acknowledges that the gamma-hydroxybutyrate anion—which is found in the patients' body following administration of Xyrem—has a short half-life. Likewise, the fact that the GBL prodrug can be made from gamma-hydroxybutyrate (*id.*) is irrelevant to the proper construction of gamma-hydroxybutyrate. And any general discussion of ionically bound gamma-hydroxybutyrate cannot be used to rewrite the claims. *Seal-Flex, Inc. v. Athletic Track and Court Const.*, 172 F.3d 836, 845 (Fed. Cir. 1999) (a party "cannot alter the plain meaning of the claim language by referring to parts of the specification out of context.").

[22] Jazz does not contend that the disputed claim terms should be interpreted differently between the '079 and '782 patents.

Jazz further complains that Avadel's proposed construction would render the asserted claims "scientifically impossible." *Supra* at 27. But the Federal Circuit "has repeatedly held that courts may not redraft claims to cure a drafting error made by the patentee, whether to make them operable or to sustain their validity." *Chef Am.*, 358 F.3d at 1374. "Even a non-sensical result does not require the court to redraft the claims…" *Id*. (internal citations omitted). Rather, where "the claim is susceptible to only one reasonable construction," the Court "must construe the claims based on the patentee's version of the claims as he himself drafted it." *Id*. Such is the case here. Jazz's construction, which "ignore[s] the explicit language of the claims," cannot be correct, even if the claims are otherwise inoperable. *Rhine v. Casio.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999).

Further, like the Sustained Release patents, any purported inoperability is again a problem of Jazz's own making. Jazz wholesale copied the claims of the Resinate patents from the claims Avadel filed in the '062 Patent family, but once again failed to consider the definition of "gamma-hydroxybutyrate" in Avadel's patent that encompassed both gamma-hydroxybutyrate ***and its salts***. Compare Ex. G (Avadel's '990 Publication), claims 1-7 with '079 patent, claims 1-7; compare Ex. H (Avadel's '866 Patent), claims 1-4 with '782 patent, claims 1-4. Thus, any inoperability results from Jazz's effort to pass off Avadel's invention as its own. The Court should decline Jazz's invitation to "redraft claims to cure [its] drafting error." *Chef Am.*, 358 F.3d at 1373.

In sum, the Resinate patents define "oxybate/gamma-hydroxybutyrate" as negatively charged ions, which are distinct from salts of oxybate. Jazz's attempts to depart from the meaning of oxybate recited in the specification, and confirmed by the claim language, should be rejected.

c) Jazz's Reply Position

The parties agree that the '079/'782 Patents provide lexicography. The question is whether the Court should read a limitation into that lexicography, as Avadel proposes. Jazz proposes that the lexicography requires only a negatively charged anion, not excluding when that negatively

charged anion is a component in an ionic bond (e.g., an oxybate resin/salt). Avadel, on the other hand, argues that the lexicography requires a negative charge of exactly -1, which in Avadel's view, would exclude oxybate salts and resins. *Id.* at 16:17-17:7, 23:17-25:7.

The exact -1 charge appears nowhere in the intrinsic record, and Dr. Klibanov admitted that the bound anion is negatively charged (*id.* at 25:2-7), which is all the lexicography requires. Importing an exact -1 limitation into the claims is error. *See Clearwater Sys. Corp. v. Evapco, Inc.*, 394 Fed. App'x 699, 706 (Fed. Cir. 2010). Indeed, Dr. Klibanov admitted that the '079/'782 specification "makes no sense" if "gamma-hydroxybutyrate" and "oxybate" are limited to just the unbound anion. Ex. 36 at 56:23-57:8, 58:2-9. Dr. Klibanov further admitted that Avadel's limited construction excludes all the patents' examples. *Id.* at 21:20-22:1, 51:1-25.

And notably, Dr. Klibanov agreed with Jazz's construction before Avadel raised this dispute. He previously submitted two reports on the '079/'782 Patents, wherein he used the disputed terms solely consistent with Jazz's construction. *See, e.g.*, Ex. 39 at ¶¶ 36, 40, 41, 45, 57, 59, 81, 85, 115, 157, 169, 207, 313. As one example, Dr. Klibanov opined on "the strong alkalinity of ***sodium oxybate*** in the [claimed] particles." Ex. 40 at ¶ 5. At deposition, Dr. Klibanov had no response other than that he could not recall the content of his validity reports, which he signed only three months ago. *See* Ex. 36 at 150:6-151:13, 118:13-136:13.

Avadel counters that because the claims refer to both "oxybate" and "sodium oxybate," the Court must construe "oxybate" to exclude sodium oxybate. Jazz already explained the flaw in Avadel's position in its opening brief (*see also* Ex. 41 at 122:4-123:4), and for the same reasons set forth above, courts should not construe claims to avoid alleged surplusage where doing so conflicts with the intrinsic record.

Further, Avadel's brief does not dispute that the claims would be "scientifically impossible" under Avadel's proposal.[23] Instead, citing *Chef America*, Avadel argues that the Court "may not redraft claims to cure a drafting error made by the patentee, whether to make them operable or to sustain their validity." Jazz is not asking the Court to redraft the claims, but rather that the Court construe the terms in the only manner supported by the intrinsic evidence and in the manner Dr. Klibanov used before Avadel sought its more limited construction. Moreover, *Chef America* is not on point. There, "the claim [was] susceptible to only one reasonable construction" (a set temperature range), and the Federal Circuit would not redraft it to avoid an undesirable result (dough burnt beyond consumption). *Chef America*, 358 F.3d at 1373-1374. "[S]ince the language in the [*Chef America*] claim was commonplace and explicitly clear, the words could only be construed to mean exactly what they stated." *Evonik Degussa GmbH v. Materia Inc.*, No. 09-636, 2013 WL 5780414, at *18 (D. Del. Sept. 30, 2013). But where, like here, the claim language (1) "is not ordinary or simple," (2) is "chemically complex," and (3) one proposed interpretation (Jazz's) would render a sensible approach while the other (Avadel's) would not, the Court should construe the claims to avoid a nonsensical result. *Id.*

d) Avadel's Sur-Reply Position

There is no dispute that the Resinate patents use lexicography to define "oxybate" as the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid, and that the claims distinguish "oxybate" and "sodium oxybate." *Supra* at 30-31. And there is no dispute that

[23] Dr. Klibanov again asserted his new "gel" theory at deposition, but pointed to a portion of the specification that discusses oxybate ***resins*** in gels, ***not*** the ***unbound anion*** in gels. Ex. 36 at 41:23-43:18, 52:9-53:9. Avadel further raised a new "liquid gel" theory at Dr. Little's deposition, which is also unsupported. *See* Ex. 41 at 135:9-139:10, 140:16-141:14.

Avadel's proposal alone tracks that definition. That should end the inquiry. *Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365, 1374 (Fed. Cir. 2006).

Rather than address that lexicography or the presumption that different terms have different meanings, Jazz resorts to asserting that Avadel's construction renders the claims inoperable. The Federal Circuit, however, has repeatedly held that the Court "may not redraft the claims to cure a drafting error" even in the face of a "non-sensical result." *Chef Am.*, 358 F.3d at 1374; *see also Lucent Techs., v. Gateway, Inc.*, 525 F.3d 1200 at 1215 (Fed. Cir. 2008) (collecting cases for the same proposition). That principle applies with particular force here, where the purportedly non-sensical result resulted from Jazz's copying of Avadel's patent claims. Ex. N (comparison between the claims of the Resinate patents, and Avadel's claims); *Supra* at 30.

Evonik, which Jazz cites to distinguish *Chef America* (*Supra* at 32), does not counsel otherwise. *Evonik* merely states that Courts should attempt to construe claims to preserve their validity when there are multiple ***reasonable*** constructions. That cannot be the case where lexicography is involved, and in the absence of alternative reasonable constructions. *Evonik* does not address circumstances where there is an explanation (copying) for why non-sensical claim language was included. The underlying assumption in *Evonik* that "the drafters of the [asserted] Patent would not intentionally draft a claim that would not make sense chemically" does not apply here.[24] 2013 WL 5780414 at *18.

Finally, Avadel is not erroneously "[i]mporting an exact -1 limitation into the claims" as Jazz contends. *Supra* at 31. That is a function of lexicography. As Dr. Klibanov explained, the

[24] It is not unreasonable per se to draft a claim covering a solid formulation of an anion, and there are many drugs on the market formulated with a free base. *See e.g.*, Ex. O at 2. Moreover, both sides' experts agree that a solid oxybate formulation can exist as a gel capsule. *See* Klibanov Tr. at 41:5-46:21; Little Tr. at 135:9-11.

lexicographic definition of "oxybate" as the "anionic form (conjugate base) of gamma-hydroxybutyric acid" refers to the unbound "oxybate" anion, which has a charge of -1. The unbound oxybate anion ceases to exist in its unbound form in sodium oxybate—sodium oxybate does not contain a moiety with a -1 charge. That the claim language recites "oxybate" and "sodium oxybate" separately further demonstrates that a POSA would understand that the latter is not included within the former in the context of the claims. Ex. C, Klibanov Decl. at ¶¶ 31-33.

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